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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,803	08/17/2006	Tsunenori Arai	081356-0266	2407

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT	PAPER NUMBER
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3769

MAIL DATE	DELIVERY MODE
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11/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,803	Applicant(s) ARAI ET AL.	
	Examiner JEFFREY B. LIPITZ	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2010 has been entered.

Response to Arguments

Applicant's arguments with respect to the drawing objections have been fully considered but they are not persuasive. Applicant asserts that original figures 2 and 7 were of sufficient quality, but does not argue that the drawings submitted June 14, 2010 are of sufficient quality. Applicant requests Examiner to identify particular aspects of the figures that should be modified. The specification describes these photographs as opened and closed and sheath removal holes. The original photographs however are largely black background with a few specks of white, while the newer photographs are just black. There are no clear designations of a surface as indicated, or of any anatomical features. These figures do NOT provide any discernable information at all. These photographs would not be permissible in any published work, because of their poor quality and resolution. If Applicant cannot figure out how to best amend them, they should be removed as they provide no value whatsoever to the application. The drawing objections have been maintained.

Applicant's arguments/amendments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to because Figures 2 and 7 are not of sufficient quality to identify any features. Corrected drawing sheets in compliance with 37 CFR 1.121 (d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121 (d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 3769

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant recites generating and transmitting the welding light through the optical fiber while the sheath and fiber are pulled away from the hole. Applicant has NO support for this recitation in the original disclosure. The closest language in the original disclosure is on pages 17-18 of the specification. The bottom of page 17 discloses slowly pulling out the fiber when the monitoring light is being radiated. Page 18 discloses pulling out the fiber/sheath after it has been determined that the fiber is in blood. Applicant never discusses pulling out the sheath/fiber during irradiation of the vessel with the welding laser.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claim 25, Applicant recites fastening the optical fiber and the sheath together. However, it is unclear from the disclosure how this step would be performed. How do the elements attached to one another? What elements enable them to be fastened together?

Art Unit: 3769

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 24, Applicant recites introducing a sheath with at a first and second optical fiber; and then discusses “an optical fiber”. It is unclear whether this optical fiber is the same as at least one of the first and second fibers. Applicant also recites “with the provisos...that when one optical fiber is employed...that when two are employed”. This statement is NOT consistent with recitation (A), which introduces a first and second optical fiber. It is unclear how many optical fibers are within the sheath, and which optical fiber performs the steps of the method. Applicant should pick one embodiment to prosecute per independent claim, rather than attempting to combine embodiments into a confusing generic claim.

Regarding claim 21, Applicant has already introduced two optical fibers in the independent claim; yet this claim recites using only one. This recitation implies that the dependent claim is broader than the independent claim. It is unclear how this claim further limits the scope of the invention.

Regarding claim 25, Applicant recites a step of “providing”, which in this case does not require a new step to be performed. If the fiber and sheath were provided as fastened together, then no step would be performed. It is unclear if this step is only

Art Unit: 3769

supposed to modify the step of “introducing”, in claim 24, or whether it is suppose to modify the method in some other manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky (5725522) in view of Hennings et al. (20050131400), hereinafter Hennings.

Regarding claims 22 and 24, Sinofsky teaches methods that repair blood vessel incisions comprising: introducing a sheath or tube or casing (70 or 81; Figures 3, 7 and 8) that includes at least one optical fiber (72 and 74; Col. 8, Lines 1-12). Illumination fibers (74) carry illumination light to the [potential] treatment area and carry reflected light back to a reflectance monitor (18; Figure 1). The monitor (18) is coupled to a display (24), which provides a visual display of the region during the procedure (Columns 5-6). Sinofsky also teaches providing welding laser light via laser port (83; Figure 3) or central fiber (72; Figures 7-8). Sinofsky does NOT explicitly teach that the monitoring step is used to determine that the tissue is a blood vessel. However, since the monitor provides a visual display to the user, it would have been obvious to a skilled artisan to check that display prior to welding the tissue.

Sinofsky does NOT teach that the sheath/optical fiber are pulled away from the hole during irradiation. Attention is directed to Hennings who teaches venous closure

Art Unit: 3769

methods/apparatuses that including providing a laser (102) delivered via a fiber optic catheter (300) and a pull-back device (104) for motorized withdrawal of the fiber optic during irradiation of the vessel wall (Abstract and Paragraph [0134]). Hennings also admits that the concept of withdrawing an emitting fiber optic was known in the prior art (Paragraph [0013]). It would have been obvious to pull the sheath/fiber away from the hole during irradiation, because doing so would help to prevent overheating of the adjacent tissue/vessel.

Regarding claim 23, Sinofsky illustrates that the distal ends of the fibers are located at the same position along the length of the sheath (Figures 3, 7 and 8).

Regarding claim 25, Sinofsky inherently discloses that the fibers and the sheath are fastened to one another, since the fibers are housed within the tubes (70 or 81) and are clearly moved with the sheath at all times.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sinofsky and Hennings as applied to claim 24 above, and further in view of Kittrell et al. (4913142), hereinafter Kittrell.

Regarding claim 21, Sinofsky and Hennings do NOT teach using one fiber for providing monitoring and treatment light. Attention is directed to Kittrell who teaches laser cauterization methods and apparatuses (Background and Summary of the Invention). The apparatus comprising: a laser or generator such as an argon laser, or a NG:YAG laser (Column 3, Lines 41; Column 7, Lines 40-56; Lines Column 24, Lines 60-69), a single optical fiber (20; Column 22, Lines 31-48; Figure 27), a beam splitter (50 or 52; Figures 21 and 22), and a detector (70 and 64), such as an array of photodiodes,

Art Unit: 3769

configured to measure the intensity of backscattered light, and a computer (80) for determining the position of an end of the welding laser transmitting means or the distance to the tissue (Column 20, Lines 37-49). Kittrell teaches supplying diagnostic or monitoring light through a selected optical fiber (20a-c), where the light falls on the tissue and is absorbed and scattered. The light then re-enters the distal ends of the various fibers (20) where it travels to the proximal end to be analyzed by a detector (64). The light may be transmitted though the same optical fiber or a different one (Column 24, Lines 17-38). It would have been obvious to use the Figure 27 apparatus of Kittrell to perform the method of Sinofsky and Hennings because it is capable of performing all of the functions of Sinofsky, but with fewer elements.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3769

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
Unit 3769